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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,622	01/28/2002	Charles Achim Bernard Boucher	DVME-1014USCON1	4855

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EXAMINER	
MAHATAN, CHANNING	
ART UNIT	**PAPER NUMBER**
1631	4

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/058,622	BOUCHER, CHARLES ACHIM BERNARD	
	Examiner	Art Unit	
	Channing S. Mahatan	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1 Sheet* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

FORM PTO-1449 Modified	Sheet 1 of 1	
List of Patents and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. DVME-1014USCON1	Serial No. Not Yet Assigned
	Applicant Charles Achim Bernard Boucher	
	Filing Date Concurrently Herewith	Group Not Yet Assigned

U.S. Patent Documents

Examiner Initial		Document No.	Date	Name	Class	Subclass
CGM	AA	5,985,559	Nov. 16, 1999	Brown	~~C12Q 1/68~~ 435	~~C12M 1/34~~ 6
	AB					

Foreign Patent Documents

Examiner Initial		Document No.	Date	Country	Translation YES	NO
	AC					
	AD					

Other Documents (Including Author, Title, Date, Pertinent Pages, Etc.)

CGM	AE	Lathrop et al., "Knowledge-based Avoidance of Drug-Resistant HIV Mutants", American Association of Artificial Intelligence, 1998, pgs 1071-1078.
	AF	Pazzani et al., "CTSHIV: A Knowledge-Based System for the Management of HIV-infected Patients", Proceedings: Intelligent Information Systems, IIS' 97 (CAT. No. 97TB100201), 1997 pgs 7-13.
	AG	Lathrop et al., "Knowledge-based Avoidance of Drug-Resistant HIV Mutants", American Association for Artificial Intelligence, Spring 1999, pgs 13-25.
	AH	Lathrop et al., "Combinatorial Optimization in Rapidly Mutating Drug-Resistant Viruses", Journal of Combinatorial Optimization, 1999, pgs 301-320.
	AI	

EXAMINER	C. Marlo	DATE CONSIDERED	July 22, 2003

DETAILED ACTION

ART UNIT DESIGNATION

The Group and/or Art Unit designated for this application has changed. Applicants are hereby informed that future correspondence regarding this application should be directed to Group Art Unit 1631.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-20.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q. 2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

LACK OF ENABLEMENT

Claims 1-20 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification describes the rules database as comprising "for each presently available drug for treatment of HIV a number of associated rules" (page 3, lines 7-10 of the Specification). "The knowledge included in the rules database is obtained from scientific articles and the like. More specifically, the rules of the database are based on the international (peer-received) scientific literature on HIV-resistance. The rules are updated frequently and the new rules reflect the latest publications on this subject." (pages 3-4, lines 32-36 and 1-2, respectively of the Specification). The described invention is based upon a set of three values that is assigned to each drug giving information about the effects sequence substitutions. A first value is indicated as resistance level (0 to 3) providing information on how much resistance is conferred on this drug by this substitution (page 5, lines 24-34 of the Specification). A second value is assigned to each drug indicating a confidence level (i.e. suggestive evidence, proven in vitro, proven in vivo) of support for this result in the scientific literature (pages 5-6, lines 35-36 and 1-7, respectively of the Specification). A third value is assigned to each drug is indicated as suitability level (0 or A, 1 or B, 2 or C, 3 or D, 4 or U) and this suitability level is based on combining and weighing the resistance level, the drug level, the confidence level and clinical experience (page 6, lines 8-26). The clinical experience can mean experience provided by experts, or it can comprise the outcome of clinical studies relating the presence of substitutions at start of therapy directly to

clinical or virological outcome (page 6, lines 27-31 of the Specification). The specification fails to provide guidance as to how the rules database is: 1) updated reflecting the latest publications on the subject; 2) how the conferred resistance by substitution is derived and then assigning a value indicative of resistance level; 3) how evidence in the scientific literature is assigned to indicate confidence level; 4) how to combine and weigh resistance level, drug level, confidence level, clinical experience to assign a value indicative of suitability. Additionally, it is unclear how clinical experience can be assessed and utilized to determine suitability. Absent from the specification are any algorithms/steps/procedures for the derivation of the first, second, and third values by conferred resistance, scientific literature, and the combination of resistance level, drug level, confidence level, and clinical experience. Thus, the original disclosure fails to provide one of skill in the art proper guidance to make and/or use the claimed method, computer program device, and computer program.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-13 and 20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Regarding claims 11 (line 3), 12 (line 4), and 13 (line 4), the phrases "for example" and "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. For claim 11: Are protease (P) substitutions and

reverse transcriptase (RT) substitutions part of the rules for different protein substitutions? For claim 12: Are the different categories in accordance with the type of drug activity 1) protease inhibitor; 2) nucleoside RT inhibitor; and 3) non-nucleoside RT inhibitor? For claim 13: Is the clade of the virus determined by genotype data? Clarification is requested, via clearer claim language. See M.P.E.P. § 2173.05(d).

Claim 20 (line 1) recites the phrase "format downloadable by a computer" which is vague and indefinite. It is unclear whether the "format downloadable" is a computer listing or computer-readable medium encoded with a computer program. Applicant is directed to the following section of the M.P.E.P. with regard to "computer programs claimed as computer listing" versus "claimed computer-readable medium encoded with a computer program":

M.P.E.P. section 2106 1(a) states:

> Similarly, computer programs claimed as computer listings per se, i.e., the descriptions or expressions of the programs, are not physical **>"things." They are neither computer components nor< statutory processes, as they are "acts" being performed. Such claimed computer programs do not define any structural and functional interrelationships between the computer program and other claimed **>elements of a computer< which permit the computer program's functionality to be realized. In contrast, a claimed computer-readable medium encoded with a computer program > is a computer element which< defines structural and functional interrelationships between the computer program and the *>rest of the computer< which permit the computer program's functionality to be realized, and is thus statutory. Accordingly, it is important to distinguish claims that define descriptive material per se from claims that define statutory inventions.

Clarification of the metes and bounds, via clearer claim language, is requested.

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 9, 11, 16 are rejected under 35 U.S.C. § 102(b) as being anticipated by Pazzani et al. (CTSHIV: A Knowledge-Based System For the Management of HIV-infected patients).

Pazzani et al. describes a rule-based system/program that recommends an individualized treatment strategy for patients (HIV), wherein the virus of the patient is monitored and the treatment strategy can be switched in response to mutations of the virus (claim 1, and 2; Abstract, lines 1-11). The system encodes rules are based upon information found in the medical literature (i.e. base substitutions/mutations for either in vitro and/or in vivo resistance to specific drugs, drug-resistant mutations, and resistance level of each drug), further, these rules rank & weight combinations of antiretroviral agents based upon antiviral activities, redundant mechanisms of action, and overlapping toxicities (claims 9, 11, and 16; Abstract; page 8, left column, lines 31-38; page 8, right column, lines 2-19). Pazzini et al. describes a computer program device and computer program implemented in JAVA (claims 19 and 20; page 8, lines 31-32; and page 9, line 18-21). Thus, Pazzini et al. anticipates the claimed invention.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: July 25, 2003

Examiner Initials: CSM

Marianne P. Allen

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